

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION**

IAN WALLACE,

Plaintiff,

vs.

PHARMA MEDICA RESEARCH, INC.; TRIS
PHARMA, INC.; ROXANE
LABORATORIES, INC.; HIKMA LABS,
INC.; and WEST-WARD COLUMBUS, INC.,

Defendants.

Cause No. 4:18-cv-01859-PLC

**DEFENDANTS' PHARMA MEDICA RESEARCH, INC., TRIS PHARMA, INC.,
ROXANE LABORATORIES, INC., HIKMA LABS, INC. AND WEST-WARD
COLUMBUS, INC.'S REPLY IN SUPPORT OF THEIR DAUBERT MOTION TO
STRIKE TESTIMONY AND OPINIONS OF DR. HARRY HULL**

COME NOW Defendants Pharma Medica Research, Inc. (“Pharma Medica”) Tris Pharma, Inc. (“Tris Pharma”), Roxane Laboratories, Hikma Labs, Inc. and West-Ward Columbus, Inc., by and through their undersigned attorneys, Hinshaw & Culbertson LLP and Terese A. Drew and Angela S. McQuage, and for their Reply in Support of their Daubert Motion to Strike Testimony and Opinions of Dr. Harry Hull, state as follows:

At the outset, Plaintiff misstated the law regarding who bore the burden of proving the admissibility of expert testimony. Plaintiff wrongly asserted Defendants argued Plaintiff had the burden of proof on causation. However, Defendants have consistently argued the burden of proving the *admissibility* of expert testimony lied with the proponent. *Becker v. Ford Motor Co.*, No. 4:07CV01573 FRB, 2010 U.S. Dist. LEXIS 160281 at 28 (E.D. Mo. Sept. 24, 2010). This premise was true even in cases where there were *res ipsa loquitor* counts. *Id.* Further, Plaintiff confused the standard for evaluating expert testimony with the standard for a motion for summary

judgment. Here, the Court did not have to review the evidence most favorable to the moving party. This was not the law and Plaintiff cited no authority to support this assertion.

Second, Plaintiff argued Dr. Hull's methodology was sound and any quibbles with Dr. Hull's methodology and the factual basis of his opinions went to the credibility of the testimony, not admissibility. However, it was the Court's responsibility to determine if the proffered expert testimony was both relevant and reliable. *Dancy v. Hyster Co.*, 127 F.3d 649, 652 (8th Cir. 1997). The main purpose was to prevent juries from being swayed by dubious testimony. *Russell v. Whirlpool Corp.*, 702 F.3d 450, 456 (8th Cir. 2012). The district court played the role of a gatekeeper to ensure an expert's testimony both rested on a reliable foundation and was relevant to the task at hand. *Id.* The gatekeeper role was mandatory, not discretionary. *Id.* citing *Daubert*, 509 U.S. at 592-93.

The screening requirement of Rule 702 boiled down to a three-part test: First, evidence based on scientific, technical, or other specialized knowledge must be **useful** to the finder of fact in deciding the ultimate issue of fact. *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 561 (8th Cir. 2014)(emphasis added). Second, the proposed witness must be **qualified** to assist the finder of fact. *Id.*(emphasis added). Third, the proposed evidence must be **reliable** or **trustworthy** in an evidentiary sense, so that, if the finder of fact accepted it as true, it provided the assistance the finder of fact required. *Id.*(emphasis added). An expert's opinion was to be based on "facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703. If an expert's opinion was so fundamentally unsupported that it could offer no assistance to the jury, it should be excluded. *Cole v. Homier Distrib. Co.*, 599 F.3d 856, 865 (8th Cir. 2010).

Plaintiff claimed Dr. Hull "methodically ruled out the other sources as possible cause of infection"; however, Dr. Hull purposefully disregarded the evidence of Dr. Heather Jordan, Dr.

Shabaz Kahn and Nurse Nancy Erickson opting to rely on Plaintiff's representations. Plaintiff argued in his responses that Dr. Hull's opinion was not based upon speculation and Plaintiff's statements but was also based upon volumes of medical records, telephone conferences and examination of Plaintiff and study records. However, when Dr. Hull's opinion was examined, his opinion was seen to inappropriately and completely disregard additional sources of Hepatitis C as well as the testimony of Dr. Heather Jordan, Dr. Shabaz Kahn and Nurse Nancy Erickson.

Despite Dr. Hull's own admission that the Hepatitis C incubation period could be longer than two (2) to twelve (12) weeks, he completely rejected any other possible sources because it did not fit into the two (2) to twelve (12) week period, in which Plaintiff participated in the Pharma Medica study wherein Plaintiff was subjected to multiple needle sticks. (See Deposition of Dr. Harry F. Hull, P. 29, L. 8-9, attached hereto as Exhibit A). Further, Dr. Hull completely discounted the Spaulding study that occurred in Dr. Hull's time period because it contained only one blood draw. (See Exhibit A, P. 33, L. 7-12). Despite Dr. Hull's own admission that it only took one contaminated blood draw to contract Hepatitis C, he refused to consider it as a possibility. (See Exhibit A P. 33, L. 16-20; P. 31, L. 17-22).

Plaintiff's own arguments could be used to discredit Dr. Hull's methodology. Specifically, Plaintiff argued that Plaintiff could have contracted Hepatitis C from any of the interns or employees because the overwhelming majority of people with Hepatitis C were asymptomatic or subclinical and thus would not know they were infected. However, Dr. Hull admitted it was possible for somebody to be screened for Hepatitis C, be positive for the virus and capable of transmitting the virus, but for some reason they had not developed the anti-bodies to Hepatitis C. (See Exhibit A, P. 58, L. 10-14). Dr. Jordan echoed Dr. Hull's testimony when she testified there were circumstances where you have an antibody test that was negative, but you might have

Hepatitis C virus in the blood. (See deposition of Dr. Heather Jordan, P. 32-33, L. 22-24; 1, attached hereto as Exhibit B). The reason Dr. Hull completely discounted any sexual encounters was because Plaintiff's girlfriend's antibody test was negative (See Exhibit A, P. 41, L. 3-15). It was possible, by Dr. Hull's own analysis, Plaintiff could have contracted Hepatitis C from a sexual encounter with someone who was asymptomatic or subclinical and did not test positive from the virus.

Additionally, Dr. Hull failed to confirm Plaintiff's assertions that he had no tattoos or piercings because he did not inspect Plaintiff's body, despite having the opportunity to do. Although Plaintiff was examined with his shirt off, there were many places Plaintiff could have a tattoo or piercing that would not be visible during that examination.

Most importantly, Plaintiff testified he had no knowledge that he was stuck with a contaminated needle. (See Deposition of Ian Wallace, P. 181, L. 5-9, attached hereto as Exhibit C). Plaintiff maintained that Defendant's expert, Nancy Erickson, stated someone, could inadvertently stick themselves and then stick a patient as she heard of inadvertent needle sticks. However, Plaintiff completely ignored Nurse Erickson's testimony that it was near impossible for Plaintiff to have been stuck with a re-used, dirty needle. (See Report of Nancy Erickson attached hereto as Exhibit D). Specifically, Nurse Erickson testified Pharma Medica used a BD Vacutainer Eclipse Blood Collection needle that had a Pre-Attached Holder for each blood draw. (See Exhibit D, P. 1). These needles contained a safety shield and were designed specifically to prevent a dirty stick from happening. (See Exhibit D, P. 1). Further, if Plaintiff was stuck with a dirty needle he likely would have been aware, as a used needle would have clotted blood and tissue within the needle, prohibiting the collection. (See Exhibit D, P. 2; See Deposition of Nancy Erickson, P. 33,

L. 14-23, attached hereto as Exhibit E). Plaintiff did not recall any issues with any blood draws in the Pharma Medica studies. (See Exhibit C, P. 64, L. 21-24).

Despite, Plaintiff and Nurse Erickson's testimony, Dr. Hull still speculated Plaintiff must have contracted Hepatitis C from the Pharma Medica studies. Plaintiff argued the Pharma Medica studies were "chaotic" with over fifty (50) people in the study, with some blood draws occurring in the dark, and with blood draws occurring once per minute. However, this description of the Pharma Medica studies was not supported by either Dr. Heather Jordan or Dr. Shabaz Kahn. Dr. Jordan, who was physically on site, testified there were supervisors present, including group leaders, a study coordinator, and quality control to confirm blood draws were being performed appropriately. (See Exhibit B, P. 136, L. 5-10; 14-16). Also, Dr. Kahn described the Pharma Medica facility not as chaotic, but as well-organized, especially with the blood sample process, with quality control on-site to ensure procedures were done correctly. (See Deposition of Dr. Shabaz Kham. P. 24, L. 10-14; P. 35, L. 17-19, attached hereto as Exhibit F). He further testified the blood samples were never done in the dark, even if blood draws had to be done in the night. (See Exhibit F, P. 35, L. 22-24).

Additionally, Plaintiff's assertion that blood draws occurred every minute was a gross misrepresentation of what actually occurred. As Dr. Shabaz testified, every procedure a person underwent was scheduled based on the scheduled dosing time and it was preferable to draw the sample on the minute. (See Exhibit F, P. 87-88, L. 22-8). However, no one testified that a blood draw occurred every single minute. In fact, Dr. Khan testified that even if the sample was not taken at the exact time, the sample would not be missed, but rather it was taken late. (See Exhibit F, P. 88, L. 17-19).

Finally, Plaintiff's assertion that a friend, who participated in a drug study at Pharma Medica stopped a phlebotomist who was attempting to draw his blood with a used needle was inadmissible hearsay and was not reliable.

Dr. Hull's testimony and opinions were not based upon supporting evidence but were based upon speculation, while relying essentially solely on Plaintiff's representations and ignoring competent evidence. As such, the result was Dr. Hull's opinions were unreliable and therefore will not offer assistance to the jury. Dr. Hull's opinions and testimony should be barred.

WHEREFORE, Defendants Pharma Medica Research, Inc., Tris Pharma, Inc., Roxane Laboratories, Inc., Hikma Labs, Inc. and West-Ward Columbus, Inc., pray this Court grant their Daubert Motion to Exclude the Expert Testimony and Expert Reports of Dr. Harry Hull relating the causation of Plaintiff's Hepatitis C, enter an order excluding such statements, testimony, and related evidence on this issue, and grant such other and further relief as this Court deemed appropriate.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was electronically filed and served to counsel via the Court's e-filing system on this 20th day of August, 2020, addressed to the following attorney(s) of record:

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